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December 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fisher's Lane, Room 10061
Rockville, MD 20852

re: Docket #97N-484S

Dear Sir:

While there are many proposed rules concerning suitability for donation of human cellular and tissue based products, there is no evidence that oocytes, embryos or isolated sperm cells used with in vitro fertilization are vectors of the diseases listed in the FDA proposal. In fact, there is no evidence that HIV has been transmitted in 21 years of IVF experience. It is unacceptable to require that embryos produced from in vitro fertilization be quarantined (frozen) for six months to prevent this theoretic condition. This proposed rule fails to appreciate that semen cryopreservation carries a much different risk for the transmission of the disease.

Quarantining of such embryos will significantly increase the cost of therapy, decrease the success rate of donor IVF, and viable embryos with be "frozen to death" by this policy. It is critically important that the FDA review this statement and identify an evidence-based recommendation.

Sincerely,

Bryan D. Cowan, M.D.
Professor and Director
Division of Reproductive Endocrinology

BDC/pkf

cc: Joyce Zeitz at ASRM

Bryan D. Cowan, MD
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